REMARKS

Applicant respectfully requests reconsideration of this application in view of these reasons.

Status of the Claims

Claims 1 and 17-24 are presented for examination on their merits. Claims 2-16 are withdrawn from consideration.

I. Double Patenting

Claims 1 and 17 - 24 stand provisionally rejected over claim 14 of commonly owned U.S. patent No. 6,232,443, read in view of Harlow and Lane, ANTIBODIES: A LABORATORY MANUAL 141 & 142 (1988), and Sambrook *et al.*, MOLECULAR CLONING: A LABORATORY MANUAL 18.70-18.75 (1989). Office Action at pages 10-12.

Applicant does not acquiesce to the examiner's rationale for rejecting these claims. In the interest of advancing prosecution, nevertheless, applicant concurrently submits a terminal disclaimer, entry of which should obviate the stated grounds for rejection. Accordingly, reconsideration and withdrawal of the rejection are requested.

II. Rejections under 35 U.S.C. § 102

(A) Claims 1, 17, 22, and 24 stand rejected for alleged anticipation by Finlay *et al.*, *J. Cell Biol.* 114: 169-83 (1991), as evidenced by Cannon *et al.*, *Urology* 69: 1227-30 (2007), and the examiner's "Appendix 1." In effect, the examiner contends that antibodies against RCCA-1 were placed in the hands of the interested public by virtue of Finlay's teaching that "polyclonal antibodies to the rat nuclear pore protein p54" were "detectably labeled with ^{125}I protein-A." Office Action at page 3, lines 10-12.

(B) Claims 1, 17, and 22-24 also are rejected over Snow *et al.*, *J. Cell Biol.* 104: 1143-56 (1987), again as evidenced by Cannon *et al.* (2007) and Appendix 1. The examiner alleges anticipation on the grounds that Snow taught that "monoclonal and polyclonal antibodies to the rat nuclear pore protein p54" were "detectably labeled with ^{125}I protein-A." *Id.* at page 5, lines 1-4.

(C) Claims 1, 18, and 22-24 stand rejected for alleged anticipation by Knapp *et al.*, U.S. patent No. 5,037,744, as evidenced by Cannon *et al.* (2007) and the examiner's "Appendix 2." In this regard, the examiner asserts that anti-RCCA-2 antibodies were accessible to the interested public because Knapp discloses "polyclonal and monoclonal antibodies to human serum albumin and detectably labeling [of such] antibodies." *Id.* at page 6, lines 14-16.

To substantiate the rejections over Finlay (A) and Snow (B), the examiner invokes Cannon for disclosing that "RCCA-1 is a differentially spliced form of Nup 54 identified by Ansorge *et al.*, which is CAD97957." *Id.* at page 5, lines 5 & 6. The examiner further alleges that "an alignment of CAD97957 with rat Nup 54 shows that the two proteins have a two regions of over 100 amino acids of nearly 100% identity." *Id.* at page 5, lines 7 & 8. Based on his perception of shared identity, the examiner concludes that "it would [have been] expected that not only polyclonal antibodies but also a substantial portion of monoclonal antibodies that bind Nup 54 will bind RCCA-1." *Id.*, lines 11-13, and Appendix 1.

Concerning the rejection over Knapp (C), the examiner contends that Cannon had identified "RCCA-2 ... as GI: 763431, which is similar to human albumin," and that "[h]uman serum albumin is 99% identical to GI: 763431 over the first 455 amino acids." *Id.*, lines 17-19. Given this understanding of the degree of sequence identity, the examiner asserts that "not only polyclonal antibodies but also a substantial portion of monoclonal antibodies that bind Nup 54 will bind GI: 763431/RCCA-2." Office Action at page 7, lines 1-2, and the examiner's "Appendix 2." Applicant respectfully traverses these rejections.

The examiner's assertion that prior-art antibodies would bind the RCCA proteins is inapposite to applicant's claimed invention, because the antibodies of that invention do not recognize prior-art proteins, such as Nup 54. Compare Office Action at page 3, lines 18 – 20, page 5, lines 11 – 13 and page 7, lines 1 – 2. Whether the prior-art antibodies bind any of the RCCA proteins is of no moment, because these antibodies also detect their respective targets in non-cancerous renal cells (see below). In sharp contrast, the claimed antibodies ***exclusively*** detect RCCA proteins in ***cancerous*** renal cells. In light of such dissimilarity in binding pattern, it necessarily follows that the claimed antibodies and the prior-art antibodies are different.

According to MPEP § 2131, a "claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior-art reference." Claim 1 is directed to antibodies that detect RCCA proteins that are "**absent in normal renal cells but present in cancerous renal cells**" (emphasis added). See also specification at page 22, lines 19-26, and Table 2. To the contrary, as noted above, all prior-art antibodies were generated using normal, non-pathological proteins as antigens, and all prior-art antibodies detect their respective target proteins in normal, non-pathological cells. See: Finlay, at page 17, right column, lines 37-45; Snow at page 1144, left column, lines 36-56, and right column, lines 8-19; and Knapp at Figure 6a.

As claimed, applicant's antibodies **do not** detect their respective targets in normal, non-pathological tissues. Failing to teach detection exclusively in cancerous renal cells, the cited art likewise fails to anticipate the claimed invention. For at least these reasons, applicant requests the rejection be withdrawn.

III. Rejection under 35 U.S.C. § 103

Claims 1, 18, and 22-24 stand rejected over Menaya *et al.* (1995) in view of Cannon *et al.*, *Urology* 69: 1227-30 (2007), plus Harlow/Lane (1988) and Sambrook *et al.* (1989), *supra*. The examiner alleges *prima facie* obviousness because, he says, Maneaya discloses Accession No. AA64922/GI: 763431 and Cannon evidences a degree of identity between RCCA-2 and GI: 763431, a protein described in Appendix 2 as "similar to human albumin." In light of this presumed identify, the examiner cites to Harlow/Lane and Sambrook for conventional antibody-production techniques, contending that, "once an antigen has been isolated, the manufacture of antibodies against it is *prima facie* obvious." Office Action at page 8, lines 18-20. Applicant respectfully traverses this rejection.

The examiner's presumption that RCCA-2 / GI: 763431 are identical is faulty, as applicant has demonstrated above. The albumin sequence of Maneaya (GI:763431) was obtained from "normal" human liver tissue, as Appendix 2 indicates, while Cannon explicitly describes RCCA-2 as an "**altered** form of albumin" found in cancerous renal tissue (page 1229 at ¶ 4; emphasis added). When Cannon is read in its entirety, therefore, it is apparent that RCCA-2 must differ from the albumin protein of "normal" cells, GI:763431.

Cannon does not identify any specific "alteration" to RCCA-2 that limits expression (and, hence, detection in accordance with this invention) to cancerous renal cells. Nor does the reference disclose the RCCA-2 sequence, *per se*. Accordingly, the prior-art fails sufficiently to describe the "altered albumin," RCCA-2, in a manner that renders the claimed antibodies obvious, within the meaning of Section 103. For at least these reasons, Applicant request the rejection be withdrawn.

CONCLUSION

Applicant submits that this application is in condition for allowance, and an early indication to this effect is respectfully requested. Examiner Reddig also is invited to contact the undersigned directly, should he feel that any issue warrants further consideration.

The Commissioner is hereby authorized to charge any additional fees, which may be required under 37 CFR §§ 1.16-1.17, and to credit any overpayment to Deposit Account No. 19-0741. Should no proper payment accompany this response, then the Commissioner is authorized to charge the unpaid amount to the same deposit account. If an extension is needed for timely acceptance of submitted papers, then Applicant hereby petitions for such extension under 37 CFR §1.136 and authorizes payment of the relevant fee(s) from the deposit account.

Respectfully submitted,

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